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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,758	10/15/2001	Wendy Naimark	10177-030-999	3968
20583	7590	07/13/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SIRMONS, KEVIN C	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,758

Applicant(s)

NAIMARK ET AL. CC

Examiner

Kevin C. Simons

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213:

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2-9, 17, 18, 34 and 35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11, 12 and 19 is/are allowed.
- 6) ☒ Claim(s) 1, 10, 13-15, 20-33 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Species in the reply filed on 3/26/04 is acknowledged. The traversal is on the ground(s) that claim 34 is generic. This is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement on 8/25/03, the election was treated as an election without traverse (MPEP § 818.03(a)). Furthermore, claim 34 is directed to further sub-species, which has micro-needles. Applicant elected the figure without micro-needles.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 14, it is unclear how there can be a point more distal than a distal end. One can go no further than the distal end of anything.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3763

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 10, 13, 15, 20-33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buirge et al U.S. Pat. No. 5,693,085.

Buirge discloses an medical device for treating body tissue of a patient comprising; an elongated member (see background of invention and fig. 7); and expandable assembly (10) and a patch having two opposing surface (12); wherein one of the opposing surface is disposed upon at least on of the wire elements (fig. 1). However, although it is clear that Buirge discloses one of the opposing surfaces comprising an adhesive material and a biologically active material (12) it is unclear if they are made separable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a separate adhesive material and biologically active material since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnman*, 168 USPQ 177, 179.

As to claim 20, (10);

As to claim 21, Buirge discloses the claimed invention except for twenty wire elements. It would have been an obvious matter of design choice to have twenty wire elements since such a modification would have involved a mere change in the number of a component. A change in the number of wire components is generally recognizes as being within the level of ordinary skill in the art.

As to claims 15-16, 22-33, (figs. 1, 3 and 5) and as to claims 10, 36, the examiner considers the basket-like expandable member to be like a basketball basket, which is open, ended on both sides.

Art Unit: 3763

Allowable Subject Matter

Claims 11, 12 and 19 are allowable over the prior art of record.

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

Drawings

The objection to the drawings has been withdrawn.

Claim Rejections - 35 USC § 112

Applicant has provided proper antecedent basis for "genetic materials". Therefore the rejection has been withdrawn.

Response to Arguments

Applicant's arguments filed 3/26/04 have been fully considered but they are not persuasive.

In response to applicant's allegations that Buirge teaches away from the present invention because the expandable assembly (stent) is separated from the catheter, therefore, the catheter is not connected to the stent. It is the examiner's position that a cap and pen assembly can be connectable and separable. Therefore, a catheter and stent assembly can be connectable and

Art Unit: 3763

separable. Thus, Buirge discloses an elongated member being connected to the expandable assembly as recited in the present claim.

In a further interpretation without the catheter, the stent 10 is clearly connected to the tube 13.

Also, Buirge clearly discloses and suggest a patch having two opposing surfaces in which one of the opposing surfaces comprises an adhesive material and biologically active material and the other opposing surface is disposed upon at least one wire element of the expandable assembly. The entire patch is made of collagen and natural materials that normally or naturally form membranes with collagen such as fibrin. Fibrin is a well-known biologically active adhesive. There is no language in the claims that precludes collagen from being on both of the opposing surfaces. Therefore, Buirge discloses the present invention.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.



Kevin C. Sirmons
Patent Examiner
7/8/04